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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,622

Applicant(s)

LAESEKE ET AL.

Examiner

Charles A. Marmor, II

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because:
 - a. In Figure 7, reference sign “60” apparently should read --61--.
 - b. In Figure 8, reference sign “60” (upper right occurrence) apparently should read --61--
and reference sign “60” (lower left occurrence) apparently should read --64--.
 - c. In Figure 9, reference sign “60” apparently should read --61--.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities:
 - a. In Paragraph [0023], line 1, “Fig. 4” (second occurrence) apparently should read
--Fig. 3--.
 - b. In Paragraph [0047], line 4, “88” apparently should read --90--.

Appropriate correction is required.

Claim Objections

3. Claim 1 is objected to because of the following informalities:

a. In line 4, “supporting” apparently should read --including-- or --having-- because the specification indicates that the introducer shaft itself is formed of a conductive metal, and there is no disclosure of a separate conductive element that is “supported” by the shaft.

b. Further regarding line 4, --adapted to be-- apparently should be inserted before “exposed”.

c. In line 5, “insulating” apparently should read --insulated-- in order to maintain consistent terminology for the limitation as used in the dependent claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The written description provides no disclosure suggesting to one of ordinary skill in the art to provide an “outer conductive covering” on the hollow tube. The specification discloses the tube as being formed of a conductive metal, and the only “coverings” mentioned in the specification are insulating materials. The description of the embodiment of the instant invention

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claimed in claim 7, occurring in Paragraph [0040], suggests only that the insulation on the outer portion of the tube is eliminated and not that a conductive covering is applied to the tube.

6. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a conductive surface that extends continuously 4mm, does not reasonably provide enablement for a conductive surface that extends continuously up to 2cm. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Lines 5-6 of Paragraph [0030] of the Specification provide that the conductive surface extends 4mm, but provide no suggestion of any other dimensions that may be appropriate. The Background of the Invention at Paragraph [0008] provides a disclosure that a known device that has “drawbacks” provides a conductive surface on a biopsy needle that extends 2cm, but there is no suggestion that these dimensions are applicable to the apparatus of the instant invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "the conductive stylet" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no conductive stylet recited in claims 1 or 6 prior to this recitation.

Claim 15 recites the limitations "the retracting mechanism" in lines 1-2 and "the schedule" in line 2. There is insufficient antecedent basis for these limitations in the claim. There is no retracting mechanism or schedule recited in claims 1, 12, 13 or 15 prior to these recitations.

Further regarding claim 15, it is believed that the claim is intended to depend on claim 14 and an amendment to correct that discrepancy would render claim 15 indefinite. The claim would be rendered indefinite because a retracting mechanism that controls the schedule for retracting, as set forth in claim 15, would make the schedule of claim 14 not "predetermined."

Claim 18 recites the limitation "the cauterizing electrical power" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no cauterizing electrical power recited in claims 16-18 prior to this recitation. It is unclear whether the cauterizing electrical power is the same as the cauterizing electrical source recited in line 3.

Claim 20 recites the limitations "the retraction of the introducer" in lines 1-2 and "the measured parameter" in line 2. There is insufficient antecedent basis for these limitations in the claim. There is no retraction of the introducer or measured parameter recited in claims 16 or 20 prior to these recitations.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claims 1-5, 7-9, 12, 13 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Eggers et al ('524). Eggers et al. teach a method and apparatus for therapeutic cauterization of predetermined volumes of biological tissue. The apparatus is a biopsy needle assembly including an introducer shaft **61** that is a hollow, electrically conductive tube. The introducer shaft is covered by an outer insulating covering **67** such that an exposed first end of the shaft forms an electrically conductive surface **65**. A biopsy needle **130** including a sampling means **131** is fit in the introducer shaft to be guided thereby. A conductive stylet **40** may be supported by the introducer shaft with an insulating covering **42** disposed between the stylet and the shaft. An indicator is provided on a control device **22** which is capable of guiding a user as to a speed of withdrawal of the introducer shaft during cauterization. The indicator is a visual display **35a-c** providing indication of electrical resistance and power at the electrically conductive surface. In operation, the introducer shaft is inserted percutaneously into a patient along an insertion path to locate the conductive surface at or in proximity to a biopsy site; the biopsy needle is guided with the introducer shaft to the biopsy shaft to obtain a tissue sample; the biopsy sample is removed from the patient; and a cauterizing electrical power source is connected to the electrically conductive surface as the introducer shaft is withdrawn to cauterize tissue along the insertion path. The cauterizing power is disconnected prior to withdrawing the conductive surface through the skin. The electrical resistance and power at the conductive surface can be measured and the withdrawal of the introducer shaft may be adjusted according to the measurements.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al ('524) in view of Ouchi ('221). Eggers et al. teach all of the limitations of the claims except that the stylet has a rounded tip. Ouchi teaches an electrocautery stylet **12** that has a hemispherical tip (figure 7). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a stylet having a rounded tip with an introducer shaft similar to that of Eggers et al. in light of the teachings of Ouchi in order to prevent unnecessary damage to the tissue and bleeding.

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al ('524) in view of Cosman ('200). Eggers et al. teach all of the limitations of the claims except that a temperature sensor is positioned on the electrically conductive surface. Cosman teaches that it is known in the art to place a temperature sensor **42** on a conductive surface of a cannula or shaft **18** in order to record lesion or body temperatures. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a temperature sensor on the electrically conductive surface of an introducer shaft similar to that of Eggers et al. in light of the teachings of Ouchi in order to determine the temperature at an electrocautery site within the body.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al ('524) in view of Moorman et al. ('033). Eggers et al. teach all of the limitations of the claims except that indicia are provided on the introducer shaft to indicate the position of the conductive surface of the introducer shaft. Moorman et al. teach a track ablation device including an introducer shaft **10** having indicia **85,86** disposed on its outer surface which allow a clinician to gauge the position of the shaft and a conductive surface of the shaft within the body. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide indicia on an introducer shaft similar to that of Eggers et al. in light of the teachings of Moorman et al. in order to indicate the location of the conductive end surface of the introducer shaft while the shaft is disposed within the body.

15. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al ('524) in view of Kieturakis ('626). Eggers et al. teach all of the limitations of the claims except that a retracting mechanism is provided to automatically retract the introducer shaft. Kieturakis teaches that it is known in the art to use a controller **150** to automatically withdraw a biopsy assembly from a patient where the assembly is withdrawn based upon various parameters. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a controller to automatically retract an introducer shaft similar to that of Eggers et al. in light of the teachings of Kieturakis in order to withdraw the introducer shaft with greater control than can be provided by manual operation.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jamshidi ('192) teaches a biopsy needle instrument for internal organ biopsy.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Examiner
Art Unit 3736

CAM
February 7, 2003